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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,518	03/09/2001	Gary Van Nest	377882001100	9215

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,518	VAN NEST, GARY	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-16,18-25,27 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-13,16,18-23,27 and 28* is/are rejected.

7)☒ Claim(s) *5,6,14,15,24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is a reply to the Paper filed 15 July 2004 in response to the Non-Final Office Action mailed 16 January 2004. Claims 1-6, 8-16, 18-25, 27, 28, 33 and 36-39 were considered in the 16 January Office Action. Claims 33 and 36-39 were canceled and claims 1, 10 and 20 were amended in the 15 July Paper. Claims 1-6, 8-16, 18-25, 27 and 28 are pending and under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

Rejection of claims 1-6, 8-16, 18-25, 27 and 28 under 35 U.S.C. §112, first paragraph, is withdrawn.

New Grounds

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 8-11, 16, 18-21, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutcherson *et al.* (1997) US Patent No. 5,663,153.

Hutcherson *et al.* teaches a method of preventing or treating an infection comprising administering an oligonucleotide to an animal, especially a human, as an immunopotentiator (see especially the paragraph bridging columns 7-8). Hutcherson *et al.* further teaches that the oligonucleotide should comprise at least one phosphate backbone modification (column 6, line 5), and contemplates the method wherein an oligonucleotide comprising between 6 and 200 nucleotides and the sequence 5'-T,C,G-3' (*i.e.*, SEQ ID NO: 2) is administered in the absence of antigen to prevent, reduce the severity of or reduce the recurrence of a symptom or HSV-1 or HSV-2 infection (see especially the paragraph bridging pages 5-6, the second paragraph in column 9, and the second and third paragraph in column 10). Although Hutcherson *et al.* does not explicitly teach administering "prior to three days after virus exposure" as recited in claim 1. The broadest reasonable interpretation of this limitation includes administration of the CpG at any point prior to three days after virus exposure and is therefore anticipated by the teaching of prophylactic exposure in Hutcherson *et al.* Thus, Hutcherson *et al.* teaches a method comprising each of the limitations of independent claims 1, 10 and 20.

Furthermore, Hutcherson *et al.* teaches the method wherein the oligonucleotide comprises the sequence 5'-T,C,G-3' according to claims 2, 11 and 21 (*Id.*); teaches administration at the site of infection according to claims 8, 18 and 27 (see especially the first full paragraph in column 8); and teaches prophylaxis or treatment of HSV-2 (*Id.*) according to claims 9, 19 and 28. Finally, although Hutcherson *et al.* does not explicitly teach reduced viral shedding according to claim 16, Hutcherson *et al.* teaches amelioration of several symptoms of HSV infection by the method (see especially columns 9-10); therefore, one of ordinary skill would reasonably expect that treatment also resulted in some reduction in the level of viral shedding.

Hutcherson *et al.* teaches a method for preventing, reducing the severity of or reducing the recurrence of a symptom of HSV infection comprising each of the limitations of the instant claims. Therefore, the claimed invention is anticipated by Hutcherson *et al.*

Claims 1-4 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner *et al.* US PG Pub No. 2004/0030118 (made of record in the IDS filed 15 July 2004).

Wagner *et al.* teaches a method of inducing immune remodeling based on the generation of immune cells through the administering CpG oligonucleotides (see especially paragraph [0075]). In paragraph [0077], Wagner *et al.* teaches that the subject receiving CpG treatment may be exposed passively to an antigen to which the subject is exposed from the environment. As discussed above, the broadest reasonable interpretation of claim 1 includes administration of the CpG at any point prior to three days after virus exposure, including prior to virus exposure in accordance with the teachings of Wagner *et al.* Wagner *et al.* also teaches that the source of the antigen can be HSV 1 and 2 (see especially paragraph [0083]), that the oligonucleotide comprises a phosphate backbone modification (see especially paragraph [0045]) and is between 6 and 200 nucleotides in length (see especially paragraph [0044]), that a herpes simplex virus antigen is not coadministered in conjunction with the composition (see especially paragraph [0120]), and that the individual is a human (see especially paragraph [0030]). Wagner *et al.* thus teaches a method comprising all of the limitations of independent claim 1.

Wagner *et al.* further teaches the method wherein the ISS comprises the sequence 5'-GACGTTCC-3' according to claims 2-4 (see paragraph [0149], especially SEQ ID NO: 71) and wherein the virus is HSV-2 (*Id.*) according to claim 9.

Wagner *et al.* teaches a method for preventing a symptom of HSV infection comprising each of the limitations of the instant claims. Therefore, the claimed invention is anticipated by Wagner *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-13, 16-23, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner *et al.* (*supra*) in view of Hutcherson *et al.* (*supra*).

As described above, Wagner *et al.* teaches a method of inducing immune remodeling based on the generation of immune cells through the administering CpG oligonucleotides for the purpose of preventing a symptom of HSV infection, which method comprises all of the limitations of the instant claims. Wagner *et al.* does not, however, teach the method wherein the

CpG oligonucleotide is administered to an individual infected with herpes simplex virus to reduce the severity or recurrence of a symptom of HSV infection.

Hutcherson *et al.* teaches that oligonucleotides capable of stimulating a local immune response are also capable of reducing the severity or recurrence of a symptom of HSV infection (see especially the section entitled "SUMMARY OF THE INVENTION" and the experiments described in columns 9-10).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to modify the teachings Wagner *et al.* to include administration of the therapeutic oligonucleotide to an individual infected with herpes simplex virus according to the method of Hutcherson *et al.*

Motivation to combine these teachings comes from the findings of Hutcherson *et al.*, which demonstrates effective treatment of HSV infection using an immunostimulatory oligonucleotide and the knowledge in the art that it is desirable to treat an existing infection as well as to attempt to prevent a symptom in an individual who has been exposed to a virus.

Absent evidence to the contrary, one would have a reasonable expectation of success in combining these teachings in view of the demonstrated effects of the immunostimulatory sequence described by Hutcherson *et al.* and the demonstrated immunostimulatory effects of the oligonucleotides of Wagner *et al.*

For these reasons, the method of independent claims 10 and 20, as a whole, would have been obvious to one of ordinary skill in the art at the time of filing. Furthermore, as described above, each of the limitations of dependent claims 11-13, 16-19, 21-23, 27 and 28 is disclosed in the teachings of Wagner *et al.* and/or Hutcherson *et al.* Thus, the method of the dependent

claims, including the method comprising administering the oligonucleotides of claims 12, 13, 22 and 23 (see Wagner *et al.* as set forth against claims 3 and 4 above), would have been *prima facie* obvious to one of ordinary skill in the art at the time of filing and the claims are properly rejected under 35 U.S.C. §103.

Allowable Subject Matter

Claims 5, 6, 14, 15, 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636